Device Safety

Collagen hemostasis devices

SMALL DEVICE, BIG RISK

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A 69-YEAR-OLD-MAN UNDERWENT A DIAGNOSTIC CARDIAC catheterization. Following the procedure, a collagen hemostasis device was inserted at the femoral arterial site to prevent bleeding.

When continuous oozing was observed at the insertion site, the physician assessed the patient and diagnosed a retroperitoneal bleed. A large hematoma pressing on the urethra caused an obstruction and subsequent kidney damage. The patient is currently on hemodialysis.

What went wrong?

A retroperitoneal bleed may develop when a collagen sealant device fails to seal the vessel properly. Possible reasons for a poor seal include improper insertion technique, patient obesity, and hypertension.

Initially, abdominal swelling and tenderness may be the only overt symptoms; pedal pulses may remain palpable and vital signs may remain within normal limits. Bleeding may not be apparent until the patient is near crisis stage.

What precautions can you take?

Review your institution's policy and training requirements in the care of patients receiving a collagen hemostasis device. Discuss risks and possible complications with your patient. Depending on your institution's policy, the use of a consent form for a collagen device may also be appropriate.

Before the procedure

- Thoroughly evaluate your patient. Locate, assess, and mark pedal pulses and document the size and shape of abdominal girth.

After the procedure

- Your patient should remain on bed rest at least 4 hours.
- Monitor his vital signs and pedal pulses for changes.
- Frequently observe the femoral arterial site for oozing, erythemia, tenderness, and swelling.
- Observe his abdomen for any changes in size, shape, or tenderness. Instruct him to alert you if he notices a change or abdominal tenderness.
- Inform the physician immediately if the patient complains of abdominal tenderness or fullness or if you detect swelling or other changes from baseline.

Although you need to support the a… …vent-reporting policy of your health care facility, you may voluntarily report a … …l device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 … 1-800-FDA-0178). The opinions and statements contained in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device *Safety* is coordinated by Chris Parmentier, RN.